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SUBJECT: ACCESSING GENETIC RESOURCES IN MEGADIVERSE PERU

REF: STATE 9667

INTRODUCTION AND SUMMARY

¶1. As one of the five most biodiverse countries on the planet, Peru has been at the forefront of international discussions on accessing genetic resources. In Peru, genetic resources are part of the national patrimony, making the national Government of Peru (GOP) responsible for their management. Peru's laws and regulations are largely based on and governed by Andean Community (CAN) norms, like Decision 391 "Common Regime on Access to Genetic Resources." In 2008 and 2009, the GOP modified its relevant laws and published genetic resources regulations complementing Decision 391. The lead agency, the Ministry of Environment, was only founded in mid-2008, so is still getting its bearings and solidifying its institutionality. While many details on specific procedures remain to be defined, Peru's new framework does provide overarching guidance on access and benefit sharing (ABS) related to genetic resources. The points of contact listed on the Convention for Biological Diversity's (CBD) website are up-to-date and knowledgeable. END INTRO AND SUMMARY.

¶2. Following are responses to reftel questions. These responses were drawn from relevant laws and regulations, as well as provided by Peru's CBD focal point for ABS, Maria Luisa del Rio, Director General of Biological Diversity in the Ministry of the Environment, on March 19, 2009.

BIOLOGICAL RESOURCES:
NORMS, AUTHORITIES & PERMITS

¶3. Research on biological resources is governed mainly by the regulations (approved by Supreme Decree 002-2009-AG in January 2009) of Peru's revised Forestry & Wildlife Law. The law specifies that the lead office for extracting forestry and wildlife resources (including for research purposes) is the Ministry of Agriculture's (MINAG) Forest and Wildlife Directorate General (www.minag.gob.pe). The competent authority for cultivated species is MINAG's National Institute for Agricultural Innovation (INIA, www.inia.gob.pe). The office that oversees and issues permits for aquatic resources is the Directorate General of

Extraction of the Ministry of Production's (PRODUCE) Vice Ministry of Fisheries (www.produce.gob.pe/portal/portal/apsportalproduce/pesqueria?ARE= 3).

¶4. The most relevant provisions are in the regulations' Title X "Forest & Wildlife Research." These articles include the designation of the Forest & Wildlife Directorate General as the competent authority for issuing forest and wildlife research permits, a requirement that researchers deposit 50% of each type of specimen of collected material at a national-level institution possessing biological collections, and a reminder that biological specimen collection or research permits do not include authorization to use the corresponding genetic resources (a separate process described below). They also state that researchers must commit to: not transfer specimens to third parties, provide three copies of the final report in Spanish, provide six copies of any resulting publications, include at least one Peruvian in the research team, among other things.

¶5. The specific procedures required to obtain permits to collect biological specimens are developed by the corresponding competent authority. These procedures are defined further in each ministry's Unique Text of Administrative Procedures (TUPA), and available on their websites. Since the law and regulations were only finalized in January 2009, most of these TUPAs are still undergoing revision.

¶6. Forestry and wildlife oversight and sanctions are defined in Title XIV of the regulations. Responsible entities include MINAG's Directorate General, OSINFOR (independent supervisory agency), the police, customs (SUNAT), and the military (for some border matters).

EXPORTING NON-CITES SPECIES

¶7. Per the Forestry & Wildlife Law regulations (Article 375), export permits for research purposes of non-CITES biological specimens are authorized by MINAG's Directorate General for Forestry & Wildlife. The Directorate General also issues non-CITES forestry and wildlife export permits for other purposes (Article 355). Export permits for components of biological diversity (seeds, specimens, etc.) do not authorize varietal improvement activities, biotech research or development, or industrial application, nor can they grant property rights on their genetic resources. The following provisions for certain commercial exports are defined in Articles 311 & 325.2:

-- for ornamental species (including ferns and bryophytes), only specimens bred in production centers that have proper management plans and export permits (approved and issued by the Regional Wildlife Authority) can be exported; and
-- exports of forest seeds are subject to the provisions of a series of listed laws and international treaties.

¶8. The corresponding detailed revised procedures, requirements and conditions for obtaining the export permits have not yet been finalized by the Directorate General. When ready, they will be included in MINAG's TUPA. In the interim, the pre-existing administrative procedures used by the predecessor Natural Resources Institute (INRENA) are in force.

IMPORTING & INTERNAL SHIPMENT
OF NON-CITES SPECIES

¶9. The non-CITES forest and wildlife import provisions (Articles 298 & 356) require a document issued by the appropriate authority in the country of origin verifying the legal rights to the specimen. They also refer to requirements contained in agricultural health laws; international agreements subscribed by Peru on biosecurity, zoosanitary and phytosanitary matters; and tax and customs provisions. The general sanitary norms must always be

followed, including when moving specimens. The competent authority is MINAG's National Agrarian Health Service (SENASA, www.senasa.gob.pe). Except for protected species, the only rules for internal/domestic shipment of research specimens are the corresponding sanitary regulations.

ACCESSING GENETIC RESOURCES

¶10. The laws and regulations pertaining to genetic resources are Andean Community (CAN) Decision 391 (available in English at www.comunidadandina.org /ingles/normativa/d391e.htm) and Peru's new Regulations for Access to Genetic Resources (hereafter "GR regs," available in Spanish at www.minam.gob.pe /index.php?option=com docman&Itemid=69). These GR regs establish the procedures to be followed in order to access genetic resources. The procedures have two phases: verification that administrative requirements have been met and negotiation with the GOP on the specific access. The final step is the signing of the access contract with the GOP and publication of the corresponding resolution. The country of origin of genetic resources must be disclosed in patent applications developed as a result of the research.

¶11. While the Environment Ministry (MINAM, www.minam.gob.pe) is the lead agency for the general framework, the competent authority for verifications and negotiations depends n the type of resource in question (Article 15 of the GR regs). For cultivated species, the authority is MINAG's National Institute for Agricultural Innovation (INIA, www.inia.gob.pe); for wildlife, it is MINAG's Forest and Wildlife Directorate General (www.minag.gob.pe), in consultation with INIA (Article 377 of Forest & Wildlife regulations); and for aquatic species, it is the Ministry of Production's (PRODUCE) Vice Ministry of Fisheries (www.produce.gob.pe/ portal/portal/apsportalproduce/ pesqueria?ARE=3). While each competent authority is responsible for negotiating and signing access contracts, the Environment Ministry must clear on the corresponding resolution before it is published. If the access request includes genetic resources from more than one sector, MINAM leads the negotiations.

¶12. Access contracts must include the following at a minimum (see Article 23 of GR regs for full list, and Article 25 for framework contracts):

-- prohibition from claiming property ownership (including intellectual property) of the genetic materials per se or derived products;
-- obligation not to transfer to third parties without authorization of competent authority;
-- recognition of the origin of the resource;
-- participation of Peruvian professionals in the collection and genetic research activities;
-- strengthening and capacity building of the support entity or resource provider (through training, equipment, infrastructure, etc.);
-- commitment to transfer scientific and technical knowledge resulting from the access activities to these professionals;
-- strengthening and capacity building of indigenous peoples and communities with respect to associated intangible components;
-- commitment to share progress, results and publications (in Spanish) with competent authority;
-- publications and reports must acknowledge Peruvian origin of the resource; and
-- economic compensation for the GOP for benefits generated from the access and use of the genetic resources.

¶13. Using these and other guidelines established by MINAM, each authority defines its specific procedures and publishes them in their Unique Text of Administrative Procedures (TUPA), found on each agency's website. Since the genetic resources and forestry & wildlife regulations were just published in 2009, most of these TUPAs are still undergoing revision. Guidelines on fair and equitable benefit sharing are also in the process of being established. Once the

revisions are complete, MINAM hopes to publish a detailed guide on accessing biological and genetic resources.

¶14. Framework access contracts, allowing multiple access to multiple resources, can be signed with universities or research centers, or with researchers that regularly access genetic resources (Title VII of GR regs). The framework contracts are for research purposes only, so access for commercial use must be specified in a separate access contract.

¶15. Supervision and sanctioning are done at the national level by the aforementioned competent authorities, following MINAM guidelines. Additional supervision mechanisms can be established in the access contracts. For example, the National Support Entity (usually a regional or local institution) can perform oversight, or visits or exchanges between providers and users of the resources can be arranged. Sanctions can include (Title X of GR regs): suspension of access, cancellation of access authorization, seizure of material, fines, ban from presenting future access requests, and cancellation of registry. Also, the GR regs (Title XI) establish a National Mechanism for the Integrated Supervision and Follow-Up of Genetic Resources under the Environment Ministry.

MAT, PIC & BENEFIT SHARING

¶16. The GR regs (Article 20) state that access contracts (signed with the GOP) and accessory contracts (signed with the land or building owner where the resource is found, conservation center, owner of the biological resource containing the genetic resource, or the national support institution) must contain provisions on prior informed consent (PIC), mutually agreed terms (MAT), and, where applicable, fair and equitable benefit sharing, in accordance with the CBD and the Bonn Guidelines. The negotiation norms, authorities and procedures are those described above. The regulations of the Forestry & Wildlife Law (Article 370) require PIC in writing for research that involves traditional knowledge of communities or individuals.

¶17. Coordinating processes for MAT and PIC regulations, issues and processes have not yet been established. However, coordination is required by the GR regs, and training of the relevant actors (MINAM, other competent agencies, native communities, customs, regional governments, etc.) is being programmed. The National Committee for Biological Diversity (CONADIB) is a multi-sectoral (government, NGOs, private sector, academia) consultative body on conservation and sustainable use of biological resources that contain genetic resources.

¶18. Recipient authorities or funds for shared financial benefits have not been specified. Non-monetary benefits are established in the access contracts, with the GOP prioritizing the capacity building of native communities and regional and local entities, particularly universities and research centers. Since the genetic resources and forestry and wildlife regulations were just approved in 2009, guidelines on fair and equitable benefit sharing are still in the process of being established.

GENETIC MATERIAL TRANSFER AGREEMENTS

¶19. Per Title IX of the GR regs, genetic material transfer agreements (MTA) are required anytime material is removed from ex-situ conservation centers. A model MTA is in the works (in line with CBD, Bonn Guidelines and the International Plant Protection Convention), but at a minimum must include conditions like:

-- forbid transfer to third parties without prior informed consent of competent authority;
-- acknowledgment of the origin of the material; and
-- prohibit user from claiming property ownership (including intellectual property) of the genetic materials or derived products.

TRADITIONAL KNOWLEDGE

¶20. If traditional (collective) knowledge is involved, there are additional requirements governed by Andean Community norms and Peru's Law 27811. The lead office on these issues is the Inventions Directorate of the National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI, www.indecopi.gob.pe/destacado-propInte-oficinas-oin-pres.jsp). By law, the Indigenous Peoples Development Fund must receive a share of financial benefits derived from the use of traditional knowledge related to biological resources. In addition to the INDECOPI office, the National Institute for Andean, Amazonian and Afroperuvian Peoples (INDEPA, www.indepa.gob.pe) manages this process and fund. The regulations of the Forestry & Wildlife Law (Article 370) require prior informed consent in writing for research that involves traditional knowledge of communities or individuals.

INFORMATION FOR RESEARCHERS

¶21. There is no handbook for researchers yet, though portions of this cable could be provided in the interim. The laws and regulations are publicly available, as are the administrative procedures (TUPAs), which are being revised to reflect the new laws and regulations.
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